IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

THE UNITED STATES OF AMERICA, et al, ex rel. STEVE GREENFIELD,	§	
Plaintiffs,	§	**CIVIL ACTION NO.1:12-cv-522**
vs.	§	
	§	The Hon. Noel L. Hillman
MEDCO HEALTH SYSTEMS, INC., ACCREDO HEALTH GROUP, INC., AND HEMOPHILIA HEALTH SERVICES, INC.	§	
Defendants.	§	

PLAINTIFF ex rel. STEVEN GREENFIELD'S RESPONSE IN OPPOSITION TO DEFENDANTS MEDCO, ACCREDO, AND HEMOPHILIA HEALTH SYSTEMS' MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

In this *qui tam* action, Relator Steven Greenfield ("Greenfield"), on behalf of the United States, has asserted and demonstrated that Accredo (and it's subsidiary HHS), a specialty pharmacy that serves, inter alia, hemophilia patients in New Jersey, violated the federal Anti-Kickback Statute ("AKS"). Accredo's violation of the AKS renders claims for reimbursement to Medicare and Medicaid false and therefore violates the False Claims Act ("FCA"). Accredo's defenses to these allegations are wholly based on several false, factually unsupported premises which are asserted in it's Motion for Summary Judgment ("MSJ").

The evidence has shown that Accredo gave remuneration totaling $2,440,844.00 dollars (*Accredo SOF ¶ 49*) in the form of substantial annual payments between 2007 and 2012 to Hemophilia Services, Inc. ("HSI") for its use and benefit and for the benefit of the Hemophilia Association of New Jersey ("HANJ), it's sister organization. This remuneration was given to induce, both directly and indirectly, recommendations and/or referrals from HANJ to its members, many of whom were beneficiaries of a Federal health care program such as Medicare, and the New Jersey hemophilia treatment centers (HTCs) treating such individuals. These actions, and the payments by Accredo to HSI violate the AKS. Accredo expressly certified in it's Provider Enrollment Agreements with the United States and in its claims for reimbursement to the Federal health care programs that they did not, and do not violate the AKS. Courts, without exception, agree that compliance with the AKS is a precondition of payment from a Federal health care program, such that liability under the FCA can be predicated on a

violation of the AKS.

Contrary to Accredo's assertions in its Statement of Facts, the evidence has demonstrated the following.

First, payments and "contributions" made by Accredo were used to fund *both* a private insurance program supported by HANJ *and* HANJ's own substantial grant program to the HTCs. HTCs heavily relied on such grants to maintain a high quality level of service and pay for operating expenses. Discovery has shown that Accredo was directly aware, based on letters and emails it received from HANJ, that it's funds were being used to support both programs.

Second, despite it's claims that the evidence has not disclosed any specific referrals that directly resulted in reimbursements from a federal health care program *(which claim is disputed)*, such evidence is unnecessary and immaterial. A violation of the AKS is not conditioned on whether the remuneration (contributions) paid by Accredo to induce referrals or recommendations was ultimately successful[1]. Greenfield need only demonstrate that *one* purposes that Accredo's contributions to HANJ was to induce referrals or recommendations for services that may be covered by a Federal care health program.

Third, it is undisputed that (i) Accredo knew and believed that HANJ was in a position of influence with the hemophilia community in New Jersey, (ii) Accredo is an

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[1] *United States of America v Picciotti*, 40 F.Supp. 2d 242, (United States District Court, New Jersey March 16, 1999). The Government need not prove that actual referrals were received, but merely solicited or received payments as an inducement. In other words, it need not prove that actual referrals were produced

approved provider with the various federal insurance programs, (iii) Accredo provides hemophilia related service to Federal health care program beneficiaries in New Jersey and (iv) Accredo has received reimbursements from Federal Health care program for its services that it has provided to those New Jersey beneficiaries for hemophilia related service.

Fourth, discovery has shown conclusively a direct connection between Accredo's payments to induce *all* of HANJ's members. HANJ created an *"HSI Approved Vendor*" program to solicit funds from New Jersey authorized home care companies, such as Accredo, who were servicing *all* hemophiliacs (those with private insurance and those who were beneficiaries of a Federal Health care plan). To participate in the *HSI Approved Vendor* program, a minimum fee of $5,000 per month was required. Thereafter, the fee was based on each homecare company's "*presence in the community*" which HANJ's Executive Director Elena Bostick viewed as "number of patients." In exchange for Accredo's payments and participation in the HSI Approved Vendor program, Accredo received positive references, HANJ's endorsement, recommendations, preferential treatment and publicity. As an example of the foregoing, HANJ identified Accredo on it's website as an "Approved Provider" *(with direct links from HANJ's website to Accredo's own website*), with a specific message on its website to its members to "*work with*" the Approved Vendors. HANJ also informed *all* of its members who the contributing Approved Vendors were, and in a letter to it's members "endorsed" Accredo and another participating Approved Vendor.

Fifth, Accredo wrongly claims that a violation of the AKS requires a wilful,

criminal intent to pay a kickback. In the context of a FCA claim, no such standard is required or was ever required. Congress and the Courts have made this clear. A defendant may violate the AKS even if he does not have actual knowledge of, or a specific intent to violate, the statute[2]

Sixth, despite claims that it "did not know" or "did not believe" that its contributions could result in violations of the AKS, as an experienced industry participant, Accredo took virtually no steps to comply with OIG Guidance to avoid a violation of the AKS. For instance, Accredo (i) excluded HANJ and HSI from the requirement that Accredo's Compliance department approve all donations,[3] (ii) from 2007 until 2011 Accredo did not require HANJ/HSI to note what specific uses HANJ or HSI planned to do with the money on their charitable request form,[4] and (iii) even though it's Charitable Contribution Policy required supporting documentation from a charity to be sent to it's legal and compliance departments, Accredo placed no controls on HANJ/HSI and did not require HANJ/HSI to certify against referrals or recommendations, or against the sharing of information for 2007 through 2010 [See Exhibit 117].

Lastly, Accredo's assertion that, since hemophilia patients, subject to insurance

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[2] See Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub.L. 111-148, Title IV, § 6402(f)(2), effective March 23, 2010. Congress has *clarified* that *Hanlester* erroneously imposed a specific intent requirement on pre-March 23, 2010 AKS violations, and that no specific intent is required to prove a pre-March 23, 2010 AKS violation

[3] See Exhibit 122

[4] See Exhibit 125

requirements, had the "ultimate choice" in which home care provider to select, no AKS could occur or was possible. This is simply wrong. It is not legally relevant or material under the AKS to prove beneficiaries were *required* to accept such referrals or recommendations.

STATEMENT OF THE FACTS

A. Procedural History

In the context of an attempt to recount the procedural history of the case, Accredo attempts to 'narrow' the scope of the Fourth Amended Complaint's ("FAC") allegations by falsely claiming that Greenfield has brought up "new" theories. This is simply wrong. After it's Order denying in part and granted in part Accredo's Motion to Dismiss, the Court directed plaintiff to file a Fourth Amended Complaint "consistent with" the Court's Opinion to serve as a "blueprint for the case going forward."[5]

The FAC, in this regard, properly alleges, inter alia, that "*the practices and activities described herein are violations of the False Claims Act in that the Defendant's actions violate the Anti-Kickback Statute and such transactions do not fall within any safe harbor provision. They, in turn, have therefore falsely certified and have caused their customers to also falsely certify that they are in compliance with the Anti-Kickback Statute*[6]*."* Accredo simply denied this assertion as a legal conclusions[7]. No objection or claim was asserted by Accredo at the time that the FAC was not consistent with the

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[5] See Opinion, Dkt. No. 50, page 33-34

[6] See Dkt. No. 52, FAC, ¶ 117

[7] See Dkt. No. 56, Answer and Affirmative Defenses ¶ 117

Court's Opinion. The FAC is based on violations of the AKS, not just select parts of the AKS that Accredo wishes to address. Greenfield is also not limited to the specific examples of fraud alleged in his complaint.[8]

B. Factual Background

As the Court is aware, Greenfield has, concurrently with Accredo, filed his own Motion for Summary Judgment. As such, this Brief[9], and any factual background provided, focuses on Greenfield's response to Accredo's Statement of Undisputed Facts and it's accompanying Brief.

1. The Hemophilia Community in New Jersey and HANJ Insurance Program

Hemophilia is a rare bleeding disorder and usually is inherited, meaning that the disorder is passed from parents to children through genes. [See Exhibit 14]. According to Accredo's Craig Mears[10], the estimated total Hemophilia population in the State of New Jersey, based on 2010 census data, was 646 patients [See Exhibit 160]. According to Bostick, HANJ has 504 member families. Because it is a rare hereditary

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[8] In the *USA ex rel Emanuele v. Medicor, Inc.*, 2014 WL 3747689 United States District Court, W.D. PA. (April 29, 2014), the Court indicated that it was *"not convinced that in qui tarn cases a relator's claim should always be viewed 'narrowly' for discovery purposes,"* . . . *The court sees no good reason to prevent a relator from discovering other examples of behavior substantially similar to those described in the complaint and that similarly fit the pattern of conduct on which the complaint is focused*.

[9] Exhibit references and sources herein begin with the Exhibits submitted with Greenfield's Motion for Summary Judgment, Exhibits 1 - 174. Additional Exhibits referenced herein with begin with Exhibit number 175

[10] Craig W. Mears was President of Hemophilia Health Services at Accredo Health Group, Inc. from August 2007 until October 2011. See Dkt. No. 52, FAC ¶ 23

disease in most cases, there can be multiple members within one family who have hemophilia [See Exhibit 26]. Based on whether the families have one or several children with hemophilia, HANJ represents a total membership of between 800 and 900 people with hemophilia. This has been consistent for several years. [See Exhibit 25].

In assessing the value of the HSI Insurance program, it is critical to understand why *all* members of HANJ highly value the Insurance Program, irrespective whether they themselves use the insurance. The vast majority of these individuals with Hemophilia were members of HANJ. The HSI Insurance program was important to all HANJ members, whether they were Federal beneficiaries or private insurance patients, regardless of their insurance because they likely knew someone[11] who was on the plan or believed that they themselves might need it someday. REDACTED

[Exhibit 70].

2. HANJ and the HTC Grant Program Funded by Accredo

The hemophilia treatment centers (HTC) are all Federally Qualified Health Care Centers designated by the State of New Jersey to provide care and treatment for people with hemophilia. Hemophilia patients visit an HTC at least once a year, unless there is some kind of trauma in between. [See Exhibit 17]. The three primary HTCs in New Jersey are (i) St. Michael's Medical Center, (ii) UMDNJ - Robert Wood Johnson

[11] Patients could be brother, cousins or related in some other ways. Many of the hemophilia patients in New Jersey knew each other. [See Exhibit 69]

University Hospital, and (iii) Newark Beth Israel Medical Center. [See Exhibit 14]. The HTCs had a list of recommended home care providers, driven in part from the HANJ (HSI Approved Vendor) list, or the State approved list. The HTCs provided information to patients so they would make a choice of company [See Exhibit 18].

HANJ began a grant program to the HTCs about 15 years ago. The HTCs provided documentation to demonstrate a shortfall in funding that was necessary to keep the centers operational. The Grant program became significant about 10 years ago. [See Exhibit 46]. During 2007 to 2012, HANJ made grants to the HTCs that totaled $1,752,022.00 dollars to Robert Wood Johnson, $980,000.00 dollars to Newark Beth Israel, and $250,000.00 dollars to St Michaels.

Accredo, despite overwhelming documentary evidence to the contrary, argues that it "believed" all of its contributions were used only to fund the HSI insurance program. Accredo denies knowing that a portion of it's funds were used to provide grants to the HTCs [Exhibit 105]. The evidence, as demonstrated herein, shows that Accredo had direct knowledge of the significant grants to HANJ and then to the HTCs that were funded, in large part, by Accredo's contributions. For instance, as early as October 1, 2009, in a email from Bostick (HANJ Executive Director) to Mears, (HHS President) regarding restoring the Accredo/HHS pledge, Bostick stated the following as reasons Mears should consider:

1. *New Jersey has four HTC's - none of which has 340B designation.*

. . .

6. ***Grants to the HTCs, for fiscal year ended 6/30/09, exceeded $500,000. These dollars enabled our centers to continue to function despite shortfalls in Government funding****. It also alleviated the need to for HTCs to explore 340B*

as a funding solution. ***[Exhibit 106****, (emphasis added)*

Then, in a letter dated October 15, 2010 from Bostick to Mears discussing the funding, Bostick advised Mears that for the fiscal year ending 6/30/10, *"HANJ awarded approximately $600,000 in grants to Hemophilia Treatment Centers . . ."* [Exhibit 107].

In May 2011, in connection with the HSI funding request, Accredo senior management (Frank Sheehy, Steve Fitzpatrick and Bruce Scott) also examined the Form 990 tax returns[12] filed by HANJ and HSI that reflected grants from HSI to HANJ over $500,000.00. [Exhibit 108].

C. The Evidence Adduced in Discovery

To defeat Accredo's MSJ, Greenfield must show that discovery has adduced sufficient evidence of an AKS violation such that a reasonable jury could return a verdict for him[13]. As summarized herein, Greenfield has identified in the record specific facts and affirmative evidence that contradict Accredo's claims. The evidence in the record clearly demonstrates that Greenfield has met this burden. Greenfield has presented evidence in the record that supports his claims of an AKS and FCA violation

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[12] See Dkt. No. 52, FAC ¶¶ 70, 71, 72. Based on 990 Tax Returns, in 2007, 2008 and 2009 HSI gave grants to HANJ each year in the amounts of $550,000, $525,000 and $500,000 respectively. In 2007, HANJ received $550,000 in grant from HSI and provided $427,102 in "various grants and allocations. In 2008, HANJ received $525,000 from HSI in gifts or grants and then gave out grants in the amount of $504,833. Likewise, in 2009, HANJ received $500,000 from HSI in gifts or grants and then gave out grants to three hemophilia treatment centers in the amounts of $200,000 to Newark Beth Israel Medical Center, $50,000 to St. Michael's Medical Center and $268,770 to Robert Wood Johnson Medical Center.

[13] *See Am. Eagle Outfitters v. Lyle & Scott Ltd.,* 584 F.3d 575, 581 (3d Cir.2009). "In making this determination, 'a court must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor.'

and also presented evidence that Accredo's defenses, that it has not violated the AKS and FCA, are wholly without support.

The "fees for services" financial arrangement between Accredo and HANJ/HSI, was based on Accredo making substantial annual payments, *one*[14] purpose of which was to induce recommendations or referrals by HANJ/HSI to it's member by designating Accredo as a "HSI Approved Vendor[15]." The designation as a "HSI Approved Vendor" included recommendations on the HANJ/HSI website, a message on the front page of the site to *"work with"* our Approved Vendors, (*with "hyperlinks" to the Accredo website*) as well as other communications from HANJ to its members.[16] In addition to the website, HANJ communicated which homecare companies were "Approved Vendors" or "Approved HSI Providers", including HHS and Accredo, to its members, HTCs, and the State of New Jersey[17].

HANJ also advised its members, including the HTCs, which corporations had donated money. [See Exhibit 103]. HANJ/HSI used the contributions primarily to fund its Grant Program to the Hemophilia Treatment Centers (HTCs) and the HSI Insurance

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[14] The AKS has long been interpreted in the Third Circuit to cover any arrangement where <u>one</u> purpose of the remuneration was to induce recommendations or referrals. *United States v. Greber,* 760 F.2d 68, 69 (3d Cir.1985).

[15] HANJ created an "HSI Approved Provider" or "HSI Approved Vendor" program that gave enhanced status to only those home care providers that agreed to pledge a minimum of $60,000 per year, or more based on their "presence in the community." [See Exhibits 33, 34, 35 and 101]

[16] See Exhibit 37 and 38

[17] See Exhibit 83, 85, and Exhibit 102,

Grant Program.[18]

It was, and is, common knowledge in the hemophilia community in New Jersey, and undisputed, that HANJ and HSI are well known influential advocates and providers of services and resources to the Hemophilia community in New Jersey. HANJ is a central resource on available services and a sponsor of an insurance grant program that provides access to health insurance.[19] HANJ's members include many of the health care providers who prescribe hemophilia factor and who provide care and support to patients and their families[20]. HANJ was also instrumental in getting home-care companies into the State of New Jersey [See Exhibit 100].

Martha Occhiogrosso, a Customer Support Representative ("CSR") for Accredo and part of the New Jersey sales team, acknowledged the benefit of being a HSI Approved Vendor and being listed on the HANJ website, stating:

> "*Being a HANJ approved provider was a good thing for HHS/Accredo because if a patient went on the HANJ website they would see the name. It was another way they (Accredo) would get new patients or they would know they (Accredo) were part of HANJ*." [See Exhibit 104]. (emphasis added)

The evidence adduced also shows that Accredo looked to measure the *quantifiable* return on investment (ROI), impact on it's market share and overall profitability from the contributions when faced with decisions to cut or increase it's contribution as described herein. [Exhibits 160-163].

This arrangement violates the AKS, and the arrangement does not fall within any

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[18] See Exhibits 46, 49-62, 67, 68, and 70

[19] See Exhibits 23, 25-27, 30-32, 67, 68, 70, 76-80,82-85

[20] See Exhibits 4-7, 23, 25-27, 30-32, 67, 68, 70, 76-80,82-85

safe harbor provision under the AKS. Whether the contributions had "other lawful purposes[21]" or whether the patient's had the ultimate "choice" as to which homecare company they selected is irrelevant as to whether the arrangement violated the AKS, and by extension, the FCA when Accredo certified its compliance with the AKS to the Federal healthcare programs.

The Medicare program requires approved providers to affirmatively certify that they have complied with the AKS. Failure to comply with the kickback laws, therefore is, in and of itself, a false statement to the government. The Federal Courts have determined that compliance with the AKS is a precondition of payment. This conclusion is "rendered inescapable when the purpose of the AKSnti–Kickback Statute is considered within the context of the Medicare statute." *42 U.S.C. § 1395y(a)(1)(A*). Courts, without exception, have long agreed that compliance with the AKS is a precondition of Medicare payment, such that liability under the FCA can be predicated on a violation of the AKS[22]. Medicare Regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In

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[21] The OIG has repeatedly stressed that a critical element of the Anti-kickback Act is violated so long as <u>*one purpose*</u> was to induce referrals or recommendations even if there may be other lawful purposes. [Advisory Opinion No. 10-19; See generally, Exhibit 169 Kevin MacAnaney Report, pages 11-12.]

[22] *See, e.g., Willis v United Health Group,* 659 F.3d 295, 304 (3d Cir. 2011) ("Compliance with the [Anti–Kickback Statute] is clearly a condition of payment under Parts C and D of Medicare); *United States ex rel. Kosenske v. Carlisle HMA, Inc.,* 554 F.3d 88, 94 (3d Cir.2009) ("Falsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act]."); *United States ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235, 243 (3d Cir.2004) ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.")

order to obtain reimbursement, and as a condition to governmental payment, providers must certify that they are in compliance with the terms in the Provider Agreement, including compliance with the AKS.

The FAC alleged that Defendants have and maintain billing privileges with Medicare, and they have admitted as much, including entering into Provider Agreements CMS Form 855s and 885b[23]. These Provider Agreements, required by Medicare regulations, contain a certification, relevant to the entire relevant period herein, that each provider must certify that they *"understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare[24]".* Accredo's actions violate the FCA, 31 U.S.C. § 3729(a)(2)[25] and §3729(a)(1)(B) in that the Defendants knowingly and falsely certified that they had complied with the AKS in order to get claims paid by Federal Health Care Programs.

STANDARD OF REVIEW

Summary judgment is appropriate where the Court is satisfied that "the

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[23] See Dkt. No. 52, FAC, ¶ 117 and Dkt. No. 56, Answer and Affirmative Defenses ¶ 117

[24] See Greenfield Exhibits 205, 206, and 207 (CMS Form 885s for the period of 04/2006 to 07/2009 which contain the required certification, See Section 15, page 26, item 3)

[25] On May 22, 2009, the Fraud Enforcement and Recovery Act (FERA) was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered certain sections.

pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) (citing FED. R. CIV. P. 56). An issue is "genuine" if it is supported by evidence such that a reasonable jury could return a verdict in the nonmoving party's favor. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the nonmoving party's evidence *'is to be believed and all justifiable inferences are to be drawn in his favor.'* " *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir.2004) (citing Anderson, 477 U.S. at 255, 106 S.Ct. 2505).

ARGUMENT

I. THERE IS EVIDENCE THAT ACCREDO VIOLATED THE AKS

In order to support its MSJ, Accredo materially and repeatedly misstates the factual record and the applicable law.

The relevant parts of the AKS (§ 1320a–7b) are as follows:

(2) Whoever **knowingly and willfully offers or pays any remuneration** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person **to induce** such person—

(A) **to refer** an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under title XVIII [42 U.S.C.A. §§ 1395 et seq.], a State health care program, **or**

(B) to purchase, lease, order, or **arrange for or recommend** purchasing, leasing, or ordering any good, facility, **service, or item for which payment may be**

made in whole or in part under title XVIII [42 U.S.C.A. §§ 1395 et seq.] or a state health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not.

The AKS has long been interpreted, in particular here in the Third Circuit, to cover any arrangement where *one* purpose of the remuneration was to obtain money for the referral or recommendation of services or to induce further referrals or recommendations. *United States v. Greber,* 760 F.2d 68, 69 (3d Cir.1985).

Accredo was part of an arrangement[26] with HSI/HANJ whereby Accredo knowingly paid substantial sums of money on an annual basis requested by HSI, for which one purpose was to induce HSI to designate Accredo (and its predecessor HHS) an "HSI Approved Vendor." Once designated as a "HSI Approved Vendor" Accredo received endorsements, recommendations and referrals to all of HANJ/HSI members, including those who are beneficiaries of a Federal health plan. These endorsements and recommendations included recommendations on the HANJ/HSI website, (*with "hyperlinks" to the Accredo website*) as well as other communications from HANJ to its members.[27] In addition to the website, HANJ communicated which homecare companies were "Approved Vendors" or "Approved HSI Providers", including HHS and Accredo, to its members, HTCs, and the State of New Jersey[28].

A. Accredo's Payments Are Remuneration Under the AKS

Accredo repeatedly misstates Greenfield's claim that the payment of the

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[26] See Exhibits 33, 34, 35 and 101

[27] See *Id*, n. 16

[28] See Exhibit 36, 83, 85, and 102

contributions was *solely* to fund a private insurance program. *(Accredo MSJ at pages 1, 10*, *11, 16*). First, the record reflects that the payments and "contributions" made by Accredo were used to *fund both* a private insurance program supported by HANJ and HANJ's own grant program to the HTCs[29], who heavily relied on such grants to maintain a high quality level of service and fund operating expenses. Discovery has repeatedly shown that Accredo was aware that its funds were being used to support both programs[30]. At this point, with its keystone premise refuted, Accredo's assertions fall apart.

However, even if it's false factual premise is accepted, a proper analysis under the AKS will still show that the payments were "remuneration," one purpose of which was to induce referrals and recommendations. Essentially, Accredo is asserting, wrongly, that the funds went to HSI and HSI used them for a private insurance program, hence, no possible AKS violation. However, the AKS, and the Courts have expressly recognized the premise of "indirect remuneration." Under the AKS, the key is not based on *how* the funds (remuneration) given were used, but on whether it was *given to induce* referrals or recommendations that may result in claims to a Federal health care program. It is undisputed that Accredo's payment of these funds were directly connected to HSI/HANJ's request and in exchange, Accredo received HSI Approved Vendor status from which Accredo, knowing the referrals and recommendations would

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[29] See Dkt. No 52, FAC at ¶ 7 ". . The second scheme involves HSI using the Medco contributions for "grants" to the designated Hemophilia Treatment Centers (HTC) in New Jersey."

[30] See Exhibits 46, 49-62, 67, 68, and 70

follow.

Courts, including this Court, have determined that *indirect* remuneration schemes, i.e, payments for one program in exchange for patient referrals from another, may violate the AKS. In *US. ex. rel. Fry,* 2008 WL 5282139, U.S.D.C., S.D. Ohio (2008), the Court addressed the issue of whether "remuneration" was received under the AKS. The Court ruled that *"compensation arrangements that take into account the volume or value of referrals or business otherwise generated between the parties*" fall "within the scope of the statute." 2008 U.S. Dist. LEXIS, at *22-23.

The United States District Court for the District of Massachusetts has cited the 1991 OIG regulation as reflecting Congressional intent. *United States v. Shaw*, 106 F.Supp.2d 103, 114 (D.Mass.2000) (“Congress's intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of *anything of value* in any form or manner whatsoever ... Moreover ... Congress prohibited transactions where there is no direct payment at all from the party receiving referrals”). [emphasis added]

This Court itself considered the issue of “indirect remuneration” in *United States of America, ex rel. Silver, et al., v. Omnicare, Inc., et al.*, (2014 WL 4827410) U.S. D.C., D.N.J.(Sept. 29, 2014). In *Silver*, the Relator filed a qui tam action for violations alleging that defendants engaged in a scheme that violated the AKS by offering nursing homes below market prices for drugs to patients insured by Medicare Part A[31] in exchange for referrals of prescriptions for nursing home patients insured by Medicare

[31] Under Medicare Part A, pursuant to the Balanced Budget Act of 1997 and in Prospective Payment System, skilled nursing facilities are paid a fixed *per diem* amount for each Medicare Part A patient, which covers the routine, ancillary, and capital-related costs associated with that patient’s stay.

Part D or by Medicaid. Specifically, the Relator alleged that Pharmerica offered commercially unreasonable, below fair-market-value prices for prescription drugs to nursing homes for the nursing homes' Part A patients, in exchange for the opportunity to provide the same drugs, at a substantially higher, market-driven cost, to the nursing home's Medicaid and Medicare Part D patients, and that Pharmerica offered prices to nursing homes which fell far below its own acquisition costs, and even further below its own total costs.

The Court found that Silver had "*adequately alleged a kickback scheme in which PharMerica knowingly offered lower priced drugs to Part A nursing home patients in exchange for the opportunity to provide the same drugs at a higher cost to the nursing home's Medicaid and Medicare Part D patients.*"

It is clear, even given Accredo's misstatement of the facts, that the funds went to HSI and HSI, even if used for a private insurance program, are still "indirect remuneration" because the funds were directly connected to HSI/HANJ's request and in exchange, Accredo received HSI Approved Vendor status, which meant, referrals, recommendations and endorsements to the *entire* HANJ membership, including Federal healthcare plan beneficiaries.

B. Contributions Were Intended To Induce Recommendation and Referrals

The AKS does not define the term "induce." However, the term "induce" has been defined to mean "[t]o bring on or about, to affect, cause, to influence to an act or course of conduct ...," Black's Law Dictionary at 775. The connection as to what "caused" or "influenced" the recommendation by HANJ/HSI is clear in the record and

comes directly from HANJ and Bostick. Bostick testified that in order to become an HSI approved vendor, the vendor (in this case, Accredo) must give a donation or pledge to HSI/ HANJ. Bostick calculated the expected pledge based on the prior year's pledge, and whether the company had expanded and become a bigger presence in the community. If they absorbed another HSI company, she added the two pledges together. Bostick defined *"presence in the community"* to mean how many other companies they acquired, how many contracts they had with insurance companies, how big their business was growing, how many patients they had and how much factor they sold [See Exhibit 33]. HSI set an "entry level pledge" of $5,000 per month ($60,000 annually) at the beginning of a contract with HSI. Bostick testified that they (the home care companies) knew this coming in. The pledge was increased when there was significant growth[32].

Bostick consistently advised Defendants that HANJ and HSI considered the payment as a "fee for services" and reiterated that belief to Greenfield and Karen Griffin[33] in a meeting on October 12, 2010 [See Exhibit 87]. Greenfield testified that he met with Mears after the meeting at HANJ to discuss what occurred. Greenfield specifically told Mears that Elena Bostick referred to "having a deal" with Mears. Greenfield testified that this alarmed him because at the same meeting, in the same context, Bostick talked about how many patients they had and how much money Accredo was making [See Exhibit 90]. Greenfield asked Mears whether he knew that

[32] See Exhibit 34

[33] Karen B. Griffin was Vice President of sales for Accredo/HHS.

Bostick was saying she had a deal with him, and Mears said, *"yes, I know"*. Greenfield took this to mean that Mears did have a deal with Bostick to make payments based on the number of patients Accredo had in New Jersey and the amount of money Accredo was making in New Jersey [See Exhibit 90]. Based on what he was told by Bostick and Mears, Greenfield understood the deal to be that Mears would make sure HANJ was paid a certain amount of dollars and in return, Accredo would in some ways receive a monopoly of the business. This would keep HANJ as one of the primary referral sources and Bostick would make sure they were continuing their business [See Exhibit 91]. This understanding is confirmed by Karen Griffin. Griffin testified that Craig Mears told her that he had described the arrangement as *"a straight quid pro quo arrangement. Give me money; you get the patients. Straight quid pro quo."* [See Exhibit 98].

C. Contributions Induced the Referrals and Recommendations

Accredo, in it's MSJ Brief (at pages 12 -15) recites four pages of case snippets discussing boilerplate law that the AKS isn't violated simply because of a "*referral*" as long as there is no "remuneration" or "inducement" (MSJ Brief at 13). We take no issue with that premise. What is shockingly lacking from Defendant is any reference to, or discussion of, the record that demonstrates there was no "inducement" for an illegal purpose. Other than their own self serving conclusionary statements, Defendants fail to address, in any substantive manner, that it knowingly paid substantial sums of money to induce HSI to designate Accredo (and its predecessor HHS) an "HSI Approved Vendor." Accredo knew that once designated as a "HSI Approved Vendor" Accredo,

would receive endorsements, recommendations and referrals to all of HANJ/HSI members, including those who beneficiaries of a Federal health insurance plan. These endorsement and recommendations included recommendations on the HANJ/HSI website, (*with "hyperlinks" to the Accredo website*)[34] with a specific message on its website to its members to "*work with*" the Approved Vendors. Accredo also fails to address that HANJ informed *all* of its members who the contributing Approved Vendors were, and in a letter to it's members "endorsed" Accredo and another participating Approved Vendor [See Greenfield Exhibit 209]. Greenfield has produced actual evidence that Accredo gave remuneration to be designated as an "Approved Provider" in which HANJ expressly endorsed Accredo to its members and requested that the members to "*work with*" the Approved Providers like Accredo.

Accredo recounts the many legitimate purposes charitable contributions, citing fostering and preserving goodwill, philanthropic interest, and supporting organizations that benefit health care organizations. Greenfield does not claim, nor does he need to prove, that the contributions did not have some legitimate purposes. Accredo is hoping that the legitimate purposes will or should act a shield against it's clearly illegal purpose. That is not the issue before the Court. The sole issue before this Court is whether Greenfield, through discovery, has adduced sufficient evidence of an AKS violation such that a reasonable jury could return a verdict for him[35]. Greenfield has identified in the record specific facts and affirmative evidence that contradicts Accredo's claims.

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[34] See *id.* n.16

[35] *See id.* n. *13*

Accredo fails to address directly or contest any of this evidence of illegal inducement. For this reason alone, Accredo's MSJ must fail.

D. Accredo's Theories Regarding the AKS are Without Merit

Accredo's defenses to the AKS, or to the evidence that has been produced in discovery, has no basis in law or fact. Rather, it is a series of tailor made factual and legal conclusions designed to fit the illegal practices which resulted in Accredo becoming the dominant[36] hemophilia home care provider in New Jersey. This is the exactly what the AKS is in place to prevent. Preservation of the public fisc would be undermined if a provider could engage in conduct warranting exclusion from the program altogether yet still demand payment until the time of formal exclusion. See *United States ex rel. Wilkins v. United Health Grp., Inc.,* No. 10–2747, 659 F.3d 295, 313–14 (3d Cir.2011); *United States v. Rogan,* 517 F.3d 449, 452 (7th Cir.2008); *Amgen,* 652 F.3d at 110–12. The AKS is intended not only to prohibit but also to prevent fraudulent conduct. *See United States v. Kruse,* 101 F.Supp.2d 410, 413 (E.D.Va.2000) (stating that the AKS's "legislative history also suggests a deterrent, and thus punitive, purpose"); H.R.Rep. No. 95–393, pt. 2, at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3040, 3047, 3050 (stating that the AKS was enacted to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the medicare and medicaid programs").

[36] A summary of all factor sales by Baxter (the primary manufacturer of "factor") that includes patients from the HTC's from 2007 through 2009 shows that by 2009 Accredo had 83% of sales. [see Dkt. No 52, FAC ¶ 105, Exhibit M]; According HHS's Craig Mears, as of the end of Q1 2011, HHS has 401 active hemophilia patients. Mears estimated HHS has a total market share of 62% *See Exhibit 7*. Bostick herself, called Accredo the "super powers" calling all the shots" *See Exhibit 140.*

Under Accredo's version of the AKS, there must be evidence of *wilful criminal intent, of providing direct remuneration, in which a referral or recommendation was directly paid for, and which resulted in a claim for reimbursement to a Federal health care provider*. Unfortunately for Accredo, this "magical" version of the AKS only exists in Accredo's "Pharma-Fantasyland"! It is the AKS adopted by Congress, which has been thoroughly reviewed by the Courts, being considered and reviewed in this case.

We address each of Accredo's claims or theories in turn below.

1. HANJ is a Referral Source.

Ignoring the evidence, and mischaracterizing the MacAnaney Report, Accredo claims HANJ's action were simply *". . . characteristic of hemophilia groups nationwide, HANJ supports and advocates for the hemophilia community*." (MSJ at 18).

a. There is evidence that HANJ made direct referrals and recommendations

Who better would know if referrals or recommendations were made, other than the Accredo's own CSRs who actually dealt with the customers directly. As stated previously, Martha Occhiogrosso, a Customer Support Representative ("CSR") for Accredo, and part of the New Jersey sales team, acknowledged the benefit of being a HSI Approved Vendor and being listed on the HANJ website, stating: "*Being a HANJ approved provider was a good thing for HHS/Accredo because if a patient went on the HANJ website they would see the name. <u>It was another way they (Accredo) would get new patients</u> or they would know they (Accredo) were part of HANJ*." [See Exhibit 104]. Ms. Occhiogrosso did not testify that they "*could*" get patients, her testimony is that they *<u>would get new</u> patients*.

On the main page of its website for 2011[37], the website HANJ/HSI states:

> ***2. <u>Remember to work with our HSI Providers</u>, as they support the New Jersey hemophilia community everyday. . . .***

On a link off of the main page, at "HSI - Services", the HANJ website states:

> ***These companies maintain the highest quality of care while providing continuity of services and constantly supporting the community in numerous ways. They consistently give back to the individuals they are servicing****. [emphasis added]*
>
> ***THE HSI APPROVED VENDORS ARE:***
>
> *Bioscrip Infusion Services*
> ***Hemophilia Health Services*** *(a/ka Accredo) [emphasis,"a/k/a" added]*
> *Bleeding Disorders Resource Network*
> *CORAM Hemophilia Services*

The identified HSI Approved Providers were listed as "hyperlinks" so that a member could simply "click" on the name of the HSI Provider and it would take them to that vendor's website. [See Certification of Counsel - Exhibit 38].

In addition, James Cline, a Accredo CSR at the time, related to the rest of the New Jersey Accredo sales team that he had spoken to HANJ and was told *"we were going to be receiving a referral from Atlantic City Medical Center for a patient that has Medicare. . . ."* after they [Atlantic City Medical Center] called HANJ to ask about homecare companies who take medicare patients and HANJ "told them about us." [See Exhibit 195 - Greenfield 00094].

HANJ also directly **endorsed Accredo** to its members. Jerry Seltzer, President of HSI, by letter dated October 2009, stated " . . . we are pleased to continue to **our**

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[37] See Exhibit 38

endorsement of two excellent homecare providers. . . "[38] (emphasis added)

b. There is evidence that HANJ made indirect referrals and recommendations

Once again, who better would know if referrals or recommendations were made than the Accredo's own CSRs and Account Managers who actually dealt with the customers directly. After Accredo attempted to cut back on its payments, in the Q4 2010 Business Plan[39] provided by Amy MacBeth, Accredo Account Manager stated the following:

> . . . . 2010 YTD - 79% of the new factor business is derived from Hemophilia Treatment Centers, and 21% is None - HTC driven. ***HHS reduction in program funding may have a significant impact on NJ HTC referring practices in Q4. Based on market intelligence, HTC's have been notified of this funding reduction and at least one HTC has begun to accelerate discussions regarding the benefits of utilizing competitive HSI providers with new patients .***

HANJ also kept the HTC's informed as which companies were on the State designated homecare list, but made a point to distinguish which of those companies "*have been approved as HSI Vendors*" and "*continually contribute to the community*." [See Exhibit 83]. Accredo sales team understood and believed that HANJ communicates with the HTC regarding the funding that Accredo provides to HANJ. [See Exhibit 84]. Bostick acknowledged that HANJ would let the HTCs know which corporations had donated money. HANJ members, and the extended community which included the hemophilia treatment centers, were notified of everything that was happening. [See Exhibit 85].

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[38] See Greenfield Exhibit 209, HANJ-PROD-00048 and 00614. (The two providers were Accredo and BioScript)

[39] See Exhibit 142

Diana Florio, Accredo VP of Sales openly acknowledged HANJ's ability to influence referrals from the HTCs in an email to Frank Sheehy, Accredo President in February 2012 after she and Amy MacBeth met with Bostick. Florio summarized the meeting and in justifying the additional commitment for 2012 for 350,000.00 dollars, Florio stated to Sheehy:

> ". . . **it is in our best interest to maintain a good relationship. They are paying premiums for over 50 of our hemophilia patients and <u>they can influence referrals from the Hemophilia Treatment Centers</u>." Exhibit 166**

2. HANJ's "Approved Provider" is a Violation of the AKS

Once again ignoring the evidence, Accredo claims that payment in exchange for designation on HANJ's "Approved Provider List" which was used to recommend and endorse such companies on the HANJ website is not a violation of the law because *"nothing in the AKS prohibits a charity from informing the public which organizations have "supported the community" by contributing to the charity.*" (*MSJ at 22*). According to Accredo, so long as Accredo does not have "control" over the patients healthcare decisions, using words like "*approved*" or even "*endorsed*" are mere "advertising activities" or "promotional materials" that do not rise to "recommendations" or "referrals". *(MSJ at 22-23*) No doubt, Accredo wishes this were so. The AKS does not limit illegal "recommendations" or "referrals" to where arrangements or transactions where there is "control" or certainty that the recommendation will actually result in a claim to a Federal health care program. This only exists in Accredo's Pharma Fantasyland.

The evidence against Accredo is significant, much of which has been recounted, but bears repeating. First, Bostick testified, and Accredo has not disputed, that a minimum payment of $5,000 per month, which increased based on number of patients

obtained was required to become an "Approved Provider[40]. This was the express condition of HANJ to become an Approved Provider.[41] Second, HANJ, which Accredo ignores, expressly asks *all* of its members to "*work with*" the Approved Providers and placed links on its own website directly to each Approved Provider[42]. We agree with Accredo in one sense. These are "advertising" and "promotional" type actions. However, it is clear that it is HANJ, after being paid by Accredo, "advertises" and "promotes" for Accredo.

To demonstrate the distinction on it's own website between just recognizing an organization who has *"supported the community*" by contributing to HANJ, and giving money to induce recommendations or referrals, we need look no further than the comparison between Baxter Pharmaceutical and the "HSI Approved Vendors." Baxter, like Accredo, has also heavily contributed to HANJ. They are a manufacturer of the factor and they are recognized on the HANJ website. They did so voluntarily and legally and were properly and legally recognized by HANJ on the website without any quid pro quo. There was no minimum payment, no "approved" status, no links to the Baxter website, no endorsement letter, and no message to members emploring the members only to use Baxter "factor." In other words, no "inducement" and no "quid pro quo."

Specifically, HANJ provides two particular services known as The PACT Program and PACT Foundation Grants. PACT stands for the Partnership for Advocacy and Communications Training (PACT). The workshop provides organizational skills,

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[40]See Exhibit 33, 34 and 35

[41] See Exhibit 33 - 36

[42] See Exhibit 38

education and advocacy for hemophilia chapters and associations. The workshop is sponsored by Baxter and it is so noted on the website, by simply stating *"HANJ, under the direction of Elena Bostick, administers both programs through Baxter Bioscience sponsored grants"* and ". . . *The PACT workshop is a one and one half day advocacy workshop, which is sponsor by an unrestricted grant from Baxter . . .* "[43]. Bostick testified that the grant was $100,000.00 dollars as long as she ran the workshop. If she conducted the workshop, she could utilize the balance how she wanted.[44]

This is the proper way, the legal and the customary way that charitable organizations recognize a company that "supports the community."

Accredo, in an attempt to distinguish it's action from "recommending" or "referring", narrows its factual arguments in a manner that would "obfuscate the purpose and meaning of the [Medicare Anti–Kickback] Act" by "splitting hairs" in attempting to narrowly construe "recommending" and/or "referring", similar to the Defendants in *Patel* and *Poulin*[45]. In reviewing the issue of the meaning of "refer" and "recommend", the *Patel* Court noted that the AKS uses but does not define the term "refer." *See 42 U.S.C. § 1320a–7(b)*. The Court began it's analysis by noting that the dispute over the meaning of the term boils down to a question of statutory interpretation. "When interpreting statutes, first and foremost, we give words their plain meaning unless doing so would frustrate the overall purpose of the statutory scheme, lead to absurd results, or contravene clearly expressed legislative intent." *United States*

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[43] See Greenfield Exhibit 204, HANJ Website at http://hanj.org/services_pact.html

[44] See Greenfield Exhibit 209, Bostick Depo., page 64, line 2-22.

[45] *United States v. Polin,* 194 F.3d 863, 866 (7th Cir.1999)

v. Vallery, 437 F.3d 626, 630 (7th Cir.2006). The Court found that if Defendant's proposed narrow definition of "refer" were the term's plain and ordinary meaning, interpreting the term "referring" as Defendant advocates would frustrate the overall purpose of the statutory scheme, lead to absurd results, and contravene clearly expressed legislative intent. In finding an expansive interpretation of what it means to "refer" that Court stated as follows:

> The overarching purpose of the statutory scheme of which the Anti–Kickback Statute is a part is to "prevent[ ] inappropriate financial considerations from influencing the amount, type, cost, or selection of the provider of medical care received by a federal health care program beneficiary." [122–1] at 5 (quoting Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, . . .* and noting that "among the evils Congress sought to prevent by enacting the kickback statutes" were "[t]he potential for increased costs to the Medicare–Medicaid system and misapplication of federal funds," as well as the improper addition of kickbacks to the "legitimate costs" of medical transactions. *United States v. Hancock,* 604 F.2d 999, 1001 (7th Cir.1979) (discussing predecessor versions of 42 U.S.C. § 1320a–7b); see also *United States v. Ruttenberg,* 625 F.2d 173, 177 (7th Cir.1980) ("Whether costs were directly and immediately increased by those particular payments, however, is irrelevant. The potential for increased costs if such 'fee' arrangements become an established and accepted method of business is clearly an evil with which the court was concerned and one Congress sought to avoid in enacting § 1320a–7b's predecessor, §1396h(b)(1).").

> Narrowly construing the term "referring" to mean only "personally directing a patient to a particular entity" is at odds with the broad nature of the statute. . . . **In *United States v. Polin*, the Seventh Circuit rejected the defendant's attempt to "obfuscate the purpose and meaning of the [Medicare Anti–Kickback] Act" by "splitting hairs" between the provision prohibiting recommending" and the provision prohibiting "referring."** *United States v. Polin,* 194 F.3d 863, 866 (7th Cir.1999). The court characterized as "apt" the Government's summation that "[r]efer is to recommend . . . " (emphasis added)

Interpreting the terms "refer" and "recommend" by their "plain meaning" in a manner that does not "frustrate the overall purpose of the statutory scheme," or "contravene clearly expressed legislative intent" is the appropriate lense in which to view whether HANJ/HSI actions constituted a "referral" or recommendation." In this

context, a plain meaning of the term "referral" is viewed as "the act of telling someone about the positive features of a person or a business, or the person who is being referred." An example of a 'referral" is telling someone why a certain person or business would be a good relationship for them to consider[46]. The Court in *Pate*l, quoting *United States v. Polin*, found that *"to refer is to recommend*." A plain meaning of the term "recommend" is viewed as "suggesting that someone or something would be good or suitable for a particular job or purpose, or to suggest that a particular action should be done.[47]"

3. HANJ's Advocacy to its Members

Accredo claims that Greenfield's theory rests on HANJ's letter to its member in March 2011 being a violation of the AKS. Accredo is mistaken. One part of Greenfield's theory is about HANJ's advocacy to it's members before and after the letter of March 2011, and what *Accredo did in response to that letter*.

First, at the highest level of Accredo, notwithstanding that the Charitable Contribution Policy of Accredo expressly states[48] that: *"while Medco encourages employees to make proposals for contributions supporting corporate objectives and strategies,* ***no employee shall . . make any connection between a request for a charitable contribution and the possibility that the applicant may promote the use of, or use, the Company's services,*** Accredo began analyzing the potential impact and loss of business that they were experiencing, and could experience, in the future.

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[46] http://www.yourdictionary.com/referral#E9KvgkC62OVXlw1j.99

[47] http://dictionary.cambridge.org/dictionary/english/recommend

[48] See Exhibit 126

From the Accredo President Frank Sheehy, to Bruce Scott, VP of Accredo and then to Craig Mears, the following questions were posed.[49] Mears then asked Greenfield to provide the answers:

1. Is there quantifiable ROI we can point to if we move from $175K to 350K?

2. What is likely business deterioration to NJ market share if we don't increase?

3. What is size of overall fund and what % does Medco contribute?

4. What % of market share do we currently have?

5. What is the YOY trend?

Second, after receiving the analysis, which showed, inter alia, that if they increased their contribution from $175,000 to $350,000 it could "*prevent potential loss of 51,538,880 units currently dispensed to patients utilizing NJ HTC's. . .*" and , "*. . . if all NJ patients are considered at Risk, this number is significantly higher . . ..* "[50]

Third, based on this analysis, Accredo restored HSI funding to $350,000 and committed to FY 2012. This was confirmed in emails between Craig Mears and Bruce Scott dates May 11, 2011, May 19, 2011 and December 9, 2011[51].

E. Accredo Acted Knowingly and Wilfully

1. The Appropriate Intent Standard Under the AKS

a. After March 23, 2010, The AKS Explicitly Does Not Require a Showing Of Specific Intent To Violate The Law

Effective March 23, 2010, Congress amended the AKS to eliminate *Hanlester's* specific intent requirement. See Patient Protection and Affordable Care Act of 2010

[49] See Exhibit 160

[50] Exhibit 160

[51] See Exhibit 163., Exhibits L-1, L-2 and L-3 to FAC, at page 2

("PPACA"), Pub.L. 111-148, Title IV, § 6402(f)(2), effective March 23, 2010. Subsection(h) of 42 U.S.C. § 1320a-7b now provides that "[w]ith respect to violations of this section, **a person need not have actual knowledge of this section or specific intent to commit a violation of this section**." *Hanlester's*[52] specific intent requirement is clearly inapplicable to this case. The *only* court of appeals to find that the pre–2010 version of the AKS required a specific intent is the Ninth Circuit *Hansleter* decision.

b. Congress's 2010 Amendment of the AKS Clarified There Was No Specific Intent Requirement in the Pre-2010 AKS

To the extent it would impose new legal standards, the 2010 PPACA amendments are not retroactive. See *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 130 S.Ct. 1396, 1400 n.1 (2010) (PPACA "makes no mention of retroactivity, which would be necessary for its application to pending cases). However, this does not mean that Congress's actions are irrelevant to the meaning of the pre-2010 AKS. *Subsequent legislation may be considered in construing an earlier statute where there are clear indications that Congress intended to clarify an erroneous court decision construing the statute*. *ABKCO Music, Inc. v. LaVere*, 217, F.3d 684, 689-92 (9th Cir. 2000), cert. denied 531 U.S. 1051 (holding that a Congressional amendment of a copyright statute clarified that a prior Ninth Circuit case had imposed an incorrect legal standard, and therefore the Congressional amendment should be applied to pending cases) *Beverly Cmty. Hosp. Ass'n v. Belshe*, 132 F.3d 1259, 1265-66 (9th Cir. 1997), cert. denied 525 U.S. 928 (1998) ("Normally, when an amendment is deemed clarifying rather than substantive, it is applied retroactively") ("a

[52] *Hanlester v. Shalala, Secretary of the Department of Health and Human Services,* 51 F.3d 1390 (Ninth Circuit 1995).

decision by the current Congress to intervene by expressly clarifying the meaning of [the earlier statute] is worthy of real deference.").

The Ninth Circuit's holding in *Hanlester*, requiring proof of specific intent to violate the pre-2010 AKS to establish a kickback violation, was contrary to the decisions of four other circuits, which held that no such showing was required. The other circuits held that to violate the AKS the defendant had only to know that his conduct was generally wrongful. See, e.g., *U.S. v. Starks*, 157 F.3d 833, 837-39 (11th Cir. 1998) (knowledge of the statute is not required for an AKS violation); *U.S. v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *U.S. v. Jain*, 93 F.3d 436, 439-41 (8th Cir.1996), cert. denied 520 U.S. 1273 (1997) (intent requirement of AKS "should only require proof that [the defendant] knew his conduct was wrongful, rather than proof that he knew it violated a 'known legal duty'"); *U.S. v. Baystate Ambulance & Hosp. Rental Service*, Inc., 874 F.2d 20, 33 (1st Cir. 1989) (upholding jury instructions that under AKS "knowingly" simply means to do something voluntarily or deliberately, not by mistake or accident; and that "willfully" means to do something purposely, with the intent to violate the law, or to do something purposely that the law forbids).

Congress's 2010 amendment of the AKS is consistent with the pre-2010 majority view that a defendant may violate the AKS even if he does not have actual knowledge of, or a specific intent to violate, the statute. The legislative history of PPACA specified that the intent of the AKS amendment was to *clarify* the Ninth Circuit's erroneous interpretation:

> The bill also addresses confusion in the case law over the appropriate meaning of "willful" conduct in health care fraud. Both the anti-kickback statute and the health care fraud statute include the term "willfully." In both contexts, the Ninth Circuit Court of Appeals has read the term to require proof that the defendant not only intended to engage in unlawful conduct,

> but also knew of the particular law in question and intended to violate that particular law. **This heightened mental state requirement may be appropriate for criminal violations of hyper-technical regulations, but it is inappropriate for these crimes, which punish simple fraud. . . . [The bill] clarifies that "willful conduct" in this context does not require proof that the defendant had actual knowledge of the law in question or specific intent to violate that law. As a result, health care fraudsters will not receive special protection they don't deserve**. 155 Cong. Rec. S10852 at S10853 (Oct. 28, 2009) (Statement of Senator Kaufman to the Committee on the Judiciary on behalf of himself and Senators Leahy, Specter, Kohl, Schumer, and Klobuchar) (discussing predecessor bill to PPACA, the Health Care Enforcement Act of 2009).[1]

Congress has *clarified* that *Hanlester* erroneously imposed a specific intent requirement on pre-March 23, 2010 AKS violations. No specific intent is required to prove a pre-March 23, 2010 AKS violation.

Accredo's actions are the epitomy of knowing and wilful conduct. Accredo did not make an "innocent mistake." They are wilful actions of Accredo management over a long period of time. However determining whether a business arrangement violates the AKS is largely a question of intent, resolution of which is the province of the trier of fact. See *United States ex rel Bartlett v.Ashcroft*, 39 F. Supp.3d 656, U.S.D.C., W.D. Pa. (2014), quoting *United States v. Dollar Bank Money Mkt. Account No.* 1591768456, 980 F.2d 233, 240 (3d Cir.1992) (explaining that "a party's mental state is inherently a question of fact which turns on credibility"

In this regard, there is ample evidence for a jury to consider whether Accredo had the requisite intent. Bostick consistently advised Accredo that HANJ and HSI considered the payment as a "fee for services" and reiterated that belief to Relator and Karen Griffin in a meeting on October 12, 2010[53]. Bostick told Greenfield and Griffin

[53] See Exhibit 87

that she and Mears had a long standing deal. Greenfield testified that he met with Mears after the meeting at HANJ to discuss what occurred, specifically that Elena Bostick referred to having a deal with Mears. Greenfield testified that this alarmed him because at the same meeting in the same context, Bostick talked about how many patients they had and how much money Accredo was making. Bostick also talked about bringing on or authorizing other vendors that could harm Accredo's business[54]. Greenfield asked Mears whether he knew that Bostick was saying she had a deal with him and Mears said, *"yes, I know"*. [See Exhibit 90]. Karen Griffin testified that Craig Mears told her that had described the arrangement as *"a straight quid pro quo arrangement. Give me money; you get the patients. Straight quid pro quo."* [See Exhibit 98] .

II. THERE IS EVIDENCE THAT ACCREDO VIOLATED THE FCA

A. Accredo's Certification of Compliance with the Anti-kickback Statute is a precondition of Medicare payment

To establish a violation of the FCA, a relator must show that the defendant knowingly made or caused to be made to an agent of the United States a false or fraudulent claim for *payment. U.S. ex rel. Wilkins v. United Health Group, Inc*., 659 F.3d 295, 304 (3d Cir.2011); *see also* 31 U.S.C. § 3729(a)(1)(A)-(B). The FCA's scienter requirement is satisfied if the defendant: (1) has actual knowledge that the claim is false; (2) acts in deliberate ignorance of the truth or falsity of the claim; or (3) acts in reckless disregard of the claim's truth or falsity. § 3729(b)(1)(A). No proof of specific intent to defraud is required. *Id.* at (b)(1)(B).

The distinguishing difference between a § 3729(a)(l)(B) violation and the above

[54] See Exhibit 90

discussed violations is the presence of the additional elements of a "false record or statement material to a false or fraudulent claim."[55] As an example, a “statement” certifying compliance with the AKS, as the case here, is a “statement” or “record” under § 3729(a)(l)(B),[56] which now reads as follows: “(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”

Courts, without exception, agree that compliance with the AKS is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the AKS[57]. Even in the absence of an express certification of compliance, the knowing submission of claims by a person who has violated a statute or regulation that contains, on its face, a direct nexus to the government's payment decision is also actionable under the FCA. *Zimme*r,386 F.3d 235 at 244.

Ignoring this overwhelming authority and consensus, Accredo claims that express certification in it’s Provider Agreement is not sufficient. Rather, Greenfield must prove, on a claim by claim basis, each claims actual connection to the violation of the AKS (MSJ at 31-33). Moreover, relying on the sole discredited *Hansleter* opinion from the Ninth Circuit, Accredo attempts to make a distinction between pre and post 2010 claims due to the clarifications under the PPACA. Here in the Third Circuit, since *Zimme*r in 2004, compliance with the AKS is and has been a precondition of Medicare

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[55] *United States ex ref. Krahling v. Ivlerck & Co., inc* 44 F. Supp. 3d 581 , 592 (E.D. Pa. 2014); *see Wilkins,* 659 F.3d at 306-07 (discussing predecessor section 3729(a)(2)).

[56] The predecessor of this section was ¶ 3729(a)(2) and was amended to correct the Supreme Court’s addition of an intent requirement in Allison Engine, Cp., v United States ex rel. Sanders, 553 U.S. 662, 671-2 (2008) and was retroactive to all claims pending on June 7, 2008.

[57] See *Id*. n. 22

payment, such that liability under the FCA can be predicated on a violation of the AKS[58]. Medicare Regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement, and as a condition to governmental payment, providers must be, and so certify that they are in compliance with the terms in the Provider Agreement.

A violation of the AKS is not conditioned on whether the remuneration paid by Accredo to induce referrals or recommendations were ultimately successful. Greenfield need only demonstrate that *one* purpose that Accredo's contributions to HANJ was to induce referrals or recommendations for services that may be covered by a Federal care health program. It is not legally relevant or material under the AKS to prove that such inducements were successful.

B. There is Conclusive Evidence that Claims Were Submitted to Federal Programs

Accredo, in the production of claims data during discovery has acknowledged through it's own expert that it did, in fact submit claims to Federal Programs and received reimbursement on these claims. During the relevant period (2007 - 2012) Defendants own expert, Wayne T. Gibson, stated in his Report that he identified 24 Federal Health care program patients, which accounted for 897 invoices, associated with patients for whom Accredo submitted claims[59] for payment to the Federal Programs of $38,694,074.00 dollars and received reimbursements for this period that

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[58] See *Id*. n. 22*;* See also Accredo Exhibits 60 -70

[59] Defendants produced CONFIDENTIAL HEALTH INFORMATION _ACC0036451.xsls which included claims data as claims with Federal Payers. This file is incorporated herein and identified in Greenfield's Counter Statement of Facts

totaled $24,917,602.00 dollars[60].

Defendants have admitted entering into Provider Agreement CMS Form 855s [61]. These Provider Agreements contain a certification that each provider must sign, and certify as follows that they *understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare*[62].

Each of each contains the following certification:

> . . . I agree to abide by all Medicare regulations, program instructions and Title XVIII of the Social Security Act. The Medicare laws, regulations and program instructions are available through the MAC. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on my compliance with all applicable conditions of participation in Medicare

Medicare Regulations also mandate the same certification for each claim that is submitted through electronic claims processing. *See* e.g. 42 C.F.R. § 423.159; 42 C.F.R. § 424.510(e).

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[60] During the relevant period (2007 - 2012) Defendants own expert, Wayne T. Gibson stated in his Report that he identified 24 Federal Health care program patients which accounted 897 invoices associated with patients for whom Accredo charged the Federal Programs $38,694,074 and received reimbursements for this period that total $24,917,602 [See Exhibit 4, Gibson Report, pages 3 of 7; page 6, n.10 and Schedule 3]. Plaintiff's expert, Albert Palentchar concluded almost identical results and analysis [See Palentchar Report, Exhibit 5]

[61] See Dkt. No. 52, FAC, ¶ 117 and Dkt. No. 56, Answer and Affirmative Defenses ¶ 117

[62] See *Id.* n 24

Whether it is through the certification in the Provider Agreement or the Medicare requirement imposed individually for each claim filed, either through an implied certification or express certification or both, Accredo cannot escape that it certified its compliance with the AKS in order to get its claims paid.

Accredo has also produced Provider Agreements and Federal claims for the period in question. Since they have been produced by Accredo itself, they are self authenticating and part of the record.

Authenticity of documents produced by a party pursuant to discovery request is sufficient foundation for a jury to determine that the document is what it is purported to be. *Lexington v. Western Pennsylvania Hospital*, 423 F.3d 318, (United States Court of Appeals, Third Circuit Sept. 9, 2005). Defendant's documents, produced by defendant in response to plaintiff's discovery request, were sufficiently authenticated so as to be admissible as part of plaintiff's summary judgment evidence. Fed. Rules Evid.Rule 901(a), (b)(4), *Federal Trade Commission v. Hughes*, 710 F.Supp. 1520 (United States District Court, N.D. Texas, Dallas Division Jan. 12, 1989).

C. Accredo Acted Knowingly

In 1986, Congress clarified the scope of "knowing" conduct that would give rise to liability under the FCA. Specifically, the House Judiciary Committee explained that the FCA is intended to reach "persons who ignore 'red flags' that the information [submitted in a claim] may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim." This definition, therefore, enables the Government not only to effectively prosecute those persons who have actual knowledge, but also those who play the 'ostrich.' "H.R.Rep. No. 660–99 (1986), at 20–21. The Committee further noted that, while "individuals and

contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek," a "rigid definition of that duty ... would ignore the wide variance of circumstances under which the Government funds its programs." *Id.* at 20. Consequently, "[o]nly those who act in 'gross negligence' of this duty will be found liable under the False Claims Act." *Id.* This is particularly here since Accredo, along with the individuals who provided evidence and testimony herein such as Craig Mears, Karen Griffin, Steve Fitzpatrick, Diana Florio, Frank Sheehy, Steve Greenfield et al are all experienced industry participants.

Kevin MacAnaney, Greenfield's liability expert has opined that, as such, Accredo should have reasonably understood that it's payments to HANJ, who was in a position to influence recommendations and referrals to Accredo's business, implicates the AKS. Accredo ignored and failed to comply with OIG Guidance and violated the AKS[63].

CONCLUSION

Overwhelming evidence and applicable law supports Greenfield's allegation. Summary judgment for Accredo should be denied.

Respectfully submitted,

s/ Marc M. Orlow Date: June 6, 2016

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[63] See Exhibit 169, MacAnaney Report, pages 5-6